

REMARKSStatus of the application

Claims 40-42, 44-45 and 48-58 are pending and stand rejected in the application. With entry of the instant response, claims 48-53 have been canceled without prejudice. The claims are canceled in order to expedite prosecution of the subject application. The claim cancellation should not be construed as acquiescence of any ground of rejections.

Applicants acknowledge with appreciation the Examiner's withdrawal of several previously rendered rejections. The following remarks are presented to address the other rejections maintained in the instant Office Action.

Rejection under 35 U.S.C. §102

The instant office action maintained the rejection of claims 48-51 as allegedly anticipated by Devanathan et al. (Proc. Nat'l. Acad. Sci. USA 87:2980-2984, 1990) and by Berthiaume et al. (Biotechnol. 12:703-706, 1994), as well as the rejection of claims 48-53 as allegedly anticipated by Wentworth et al. (Proc. Natl. Acad. Sci. USA 97:10930-5, 2000) in light of Scripps Press Release (November 14, 2002).

For the reasons advanced in Applicants previous responses, Applicants cannot agree to the Examiner's rationale in maintaining these rejections. Nevertheless, in an effort to facilitate prosecution of the subject application, Applicants have herein canceled claims 48-53. The instant rejections are therefore moot.

Written description rejection under 35 U.S.C. §112, 1st paragraph

The office action further maintained the rejection of claims 40-42, 44, 45 and 54-58 as allegedly failing to comply with the

written description requirement. The Examiner asserts that Applicants did not provide support in the specification for the recitation of "or another molecule" in the claims. Referring to some disclosures in the specification (page 78, lines 1-4; page 83, lines 11-18; and page 93, lines 17-24), the Examiner additionally alleges that the specification only discloses a singlet oxygen source being conjugated to the antibody. As such, the Examiner concludes that the recitation of the singlet oxygen source being not conjugated to the antibody constitutes new matter. Finally, the Examiner notes that the mere absence of a positive recitation is not a basis for exclusion. For the reasons set forth in Applicants' previous responses and the additional remarks presented below, Applicants respectfully traverse this rejection.

A. Disclosure of embodiments wherein singlet oxygen source is not conjugated to antibody or another molecule

Applicants do not understand the Examiner's basis for asserting that the specification only disclosed singlet oxygen sources being conjugated to the recited antibody, and that there is no support for the recitation of "or another molecule." It appears the Examiner has overlooked Applicants' previous submissions concerning support for the claim limitations currently at issue. Applicants accordingly request the Examiner to reconsider Applicants' arguments as reiterated below. If the Examiner nonetheless takes the position that the subject specification does not provide support for the recitation of a source of singlet oxygen not conjugated to an antibody or another molecule, Applicants respectfully request a clarification from the Examiner.

First, Applicants wish to remind that Examiner that written description does not require verbatim and literal support in a patent specification. Rather, it is well established that written description requirement "does not require in haec verba antecedence in the specification." *Staehelin v. Secher*, 24 USPQ2d 1111, 1117 (Fed. Cir. 1991; emphasis added). If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met. *In re Alton*, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996; emphasis added). Consistent with the case law, the MPEP also states that "[t]he subject matter of the claim need not be described literally (i.e., using the same terms or in haec verba) in order for the disclosure to satisfy the description requirement." (MPEP § 2163.02; emphasis added). Further, other than express disclosure, claim limitations can also be supported in the specification by implicit or inherent disclosure (See, e.g., MPEP. § 2163-I-B).

In the present case, Applicants acknowledge that the specification has disclosed embodiments in which the source of singlet oxygen is conjugated to the antibody. However, contrary to the Examiner's assertions, disclosure of the subject specification is not limited to these embodiments. Rather, in some other embodiments disclosed in the specification, the source of singlet oxygen is clearly not conjugated to the antibody or another molecule. Consistently, the specification at page 25, line 4 merely states that "in some embodiments" (i.e., not all) a sensitizer is conjugated to an antibody. This clearly implies that there are some other embodiments in which the source of

singlet oxygen is not conjugated to the antibody. This is further evidenced by specific embodiments in which the source of singlet oxygen is not conjugated to the antibody. For example, as pointed out in Applicants' previous responses, Example III and FIG. 14A-D explicitly illustrate use of source of singlet oxygen that is not covalently attached to the antibody. There, the specification described a typical bactericidal assays:

In a typical experiment, a culture of E. coli (in log phase growth, $OD_{600}=0.2-0.3$) was repeatedly pelleted ($3 \times 3,500$ rpm) and resuspended in PBS (pH 7.4). The PBS suspended cells were then added to glass vials and cooled to 4°C. Hematoporphyrin IX (40 μ M) and antibody (20 μ M) were added... (see page 77, line 28 to page 28, line 2; emphasis added)

In this passage of the specification, the concentrations of antibody (20 μ M) and hematoporphyrin (40 μ M) are different and separately described. These disclosures clearly indicate that the source of singlet oxygen (hematoporphyrin) is not conjugated to the antibody or another molecule. Similar embodiments wherein the source of singlet oxygen is not conjugated to the antibody or another molecule are also described in Examples I and II. See, e.g., page 48, lines 19-21 (mixing horse IgG at a concentration of 6.7 μ M and hematoporphrin IX at a concentration of 40 μ M); page 49, lines 7-10 (sheep IgG at 20 μ M and a chemical source of singlet oxygen at 25 mM); and page 60, lines 11-13 (horse IgG at 50 mM and hematoporphrin IX at 40 μ M). Thus, the subject specification has clearly described methods for generating reactive oxygen species and for killing bacterial with a source of singlet oxygen that is not conjugated to an antibody or another molecule. At the minimum, these disclosures provide

implicit or inherent support for embodiments wherein the source of singlet oxygen is not conjugated to the antibody (or another molecule). The law of written description does not ask anything more than such disclosure in order to satisfy the description and support requirement under 35 U.S.C. § 112.

B. Negative limitation

In maintaining the instant rejection, the Examiner appears to be primarily concerned with the negative limitation recited in the pending claims. As explained below, contrary to the Examiner's assertion, the claim limitation that the singlet oxygen source is not conjugated to the antibody or another molecule is not based on "the mere absence of a positive recitation."

According to MPEP 2173.05(I), a negative limitation is proper if (1) the scope of the claim is clear and definite in spite of the negative limitation; and (2) the negative limitation has basis in the original disclosure. As an example, the MPEP notes that "[a] claim which recited the limitation 'said homopolymer being free from the proteins, soaps, resins, and sugars present in natural Hevea rubber' in order to exclude the characteristics of the prior art product, was considered definite because each recited limitation was definite." See, MPEP 2173.05(I); quoting *In re Wakefield*, 422 F.2d 897, 899, 904, 164 USPQ 636, 638, 641 (CCPA 1970).

Applying this test to the instant case, the presently claimed invention undoubtedly satisfy these criteria in the recitation of the claim limitation "not conjugated to the antibody or another molecule." First, with insertion of the noted limitation, the claims only encompass the use of a singlet oxygen source that is not conjugated to the recited antibody or

any other molecules (i.e., in a free state). By clearly setting forth what is intended to be protected, the present claims are quite analogous to the claim in the above noted specific example described in the MPEP. In specifying that the source of singlet oxygen is not conjugated to the antibody or another molecule, any use of a source of singlet oxygen conjugated to a second molecule is thus excluded from the claimed invention. As such, the negative claim limitation merely defines the scope of the claim within a narrower and clearly defined boundary. As the Examiner would not dispute, the scope of the present claims remains clear and definite upon introduction of the negative limitation.

The next issue is whether there is basis in the specification for the recited negative limitation. To this end, it must be noted that an inherent or implicit disclosure should not be confused with an absence of disclosure. As clarified above, the specification has at least implicitly or inherently (if not expressly) disclosed that the source of singlet oxygen is not conjugated to the antibody (or other molecules). The actual embodiments (e.g., shown in Example III) wherein the source of singlet oxygen is not conjugated to the antibody or another molecule are certainly not "a mere absence of positive recitation." In other words, the presently recited negative limitation does have basis in the specification. Therefore, the inclusion of the negative claim limitation in the present claims is proper.

To summarize, the subject specification has adequate support for the recitation that the source of singlet oxygen is not conjugated to the antibody (or another molecule). In addition, the boundary of the claims is by no means rendered indefinite by the negative claim limitation. Therefore, the presently claimed invention satisfies the written description requirement and does

not contain new matter. Accordingly, the instant rejection should be withdrawn.

CONCLUSION

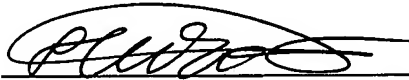
In view of the foregoing, Applicants respectfully submit that the claims now pending in the subject patent application are in condition for allowance, and notification to that effect is earnestly requested. If needed, the Examiner is invited to telephone Applicant's attorney at (858) 784-2937 to facilitate prosecution of this application.

The Director is hereby authorized to charge our Deposit Account No. 19-0962 in the event that there are any additional charges associated with the present Petition or any Response in connection with this application.

Respectfully submitted,

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Date



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